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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,557	02/10/2004	Peter Nash	C150.12.4	1455

7590 01/25/2011

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
01/25/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,557	NASH ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-66 and 73-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *62-66 and 73-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/3/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed November 9, 2010 has been entered. Claims 61-66 have been amended. Claims 1-60 and 67-72 are cancelled. Claims 73-81 are newly added. Claims 61-66 and 73-81 are under consideration in this Office action.

Withdrawal of Objections and Rejections

2. The following rejections have been withdrawn in view of applicants' amendments:

a) The rejection of claims 61, 65, 67-68, 70 and 72 under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., and Emery et al., in view of Van Donkersgoed et al;

b) The rejection of claims 66 and 71 under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., Emery et al., and Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Kirkwood et al;

c) The rejection of claims 64 and 69 under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., Emery et al., and Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Nash et al;

d) The rejection of claim 63 under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., Emery et al., Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Smith et al.

Response to Arguments

3. Applicant's arguments with respect to claims 61-66 and 73-81 have been considered but are moot in view of the new grounds of rejection.

New Grounds of Rejection Necessitated By Amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 61, 65-66, 73-76, 79 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., (US Patent 4,748,018 published May 31, 1988) and Van Donkersgoed et al. (Can Vet. J. Vol. 36. July 1995. pages 425-429).

The claims are drawn to a method of decreasing respiratory illnesses in animals comprising: inhibiting the ability of microbial organisms causing respiratory illness to adhere and multiply in the animals' respiratory tract wherein the inhibition is generated by spraying the contents of an egg mixture comprising adherence inhibiting material produced in eggs laid by female birds, the birds inoculated with an organism mixture comprising one or more microbial organisms causing respiratory illness, wherein the egg mixture is sprayed into the respiratory tract of the animal to produce a mist that coats the nasopharynx of the respiratory tract and prevents the microbial organisms

causing respiratory illness from adhering to the mucous membrane and bronchi and alveolar cells of the animals respiratory tract.

Stolle et al., (US Patent 4,748,018) teach a method for passively immunizing a mammal with heterologous antibody obtained from an immunized domesticated fowl, which has been immunized against an antigenic substance (col.1 lines 10-13, col. 3, lines 39-45). Stolle et al., teach that antibody produced in one species can be used to neutralize the effects of the corresponding antigen in the other species , thus passive immunization occurs when an individual from one species receives immune protection from antibodies produced in an individual of another species (col. 1, lines 37-42).

Stolle et al., teach the method comprises feeding a mammal a material having an enhanced antibody titer against said antigen obtained from the egg of domesticated fowl immunized against the antigen, and administering to the mammal an immunologically effective amount of an antibody from the domesticated fowl (col. 3, lines 53-61).

Any mammal can be treated, the mammals include domesticated mammal such as rabbits, cows, horses, goats, sheep, husbandry animals, and non-domesticated mammals such as monkey and apes, and human beings (col. 4, lines 61-68).

Any antigen or combination of antigens can be employed, where the antigen can be bacterial, viral, cellular or any other substance to which the immune system of the fowl will respond (col. 5, lines 1-5). Suitable antigens can include *Pasteurella haemolytica, Pasteurella multicoda* and several *Haemophilus* species, along with a wide variety of other known viral antigens (col. 5 lines 10-35).

The material fed to the mammal should be normal egg or may have an enhanced titer against the antigens, where the material can either the whole egg, r fractions thereof, such as egg yolk (col. 6, lines 4-7). Additionally, the material should be such that the avian antibody has not lost its immunological effect and should not have become denatured (col. 6, lines 7-14).

The method teaches feeding the mammal a material having an enhanced antibody titer against an antigen obtained from the egg of fowl immunized against the antigen and administering to the mammal an immunologically effective amount of antibody (col. 3, lines 50-65). Example 1 teaches using mixed bacterial strains for inoculation of the birds. Stolle et al., teach antigen selection; sensitatization of the domesticated fowl by primary immunization; testing of the eggs or serum to confirm sensitivity induction; administration of boosters to induce and maintained an antibody producing state; testing of the antibody level in the egg yolk; and collecting the eggs during its immunized state (col. 7-8, lines 25-35). The purified antibody has been sterilized and subjected to filtration (col. 8, lines 30-35). Stolle et al., teach preparation by way of pasteurization of immune milk containing enhanced antibodies (col. 8, lines 42-54). The egg product or antibody comprises a parenteral carrier (col. 4, line 18).

This method is applicable to human beings also (col. 4, lines 66-68). Modes of administration include oral and parenteral administration (col. 6, lines 40-45). It is noted that parenteral administration involves piercing the skin or mucous membrane, while oral administration includes administration to the enteral/digestive tracts and respiratory tracts (including bronchi, alveolar sacs and alveoli) using liquids, such as inhalers,

nebulizers, vaporizers, and the like. Oral administration can also be effectively used to treat diseases (col. 6, lines 45-46). Stolle et al., teach the typical administration for preventative treatment of infectious disease and palliative treatments such as treatment to a given infection or disease (col. 7, lines 12-18). Stolle et al., teach those of skill in the art can readily ascertain the amount of egg product, or avian antibody, to give to the mammalian subject (col. 7, lines 8-11). Stolle et al., teach the compositions can bee used in the form of premixed food products such dehydrated immune milk or egg materials and can be mixed and used either in the feeding stage or administration stage (col. 9, lines 4-9). However, Stolle et al., does not specific recite which antigens can be used for decreasing respiratory illness in animals.

Van Donkersgoed et al., teach enzootic pneumonia, a respiratory disease, occurs frequently in beef and diary calves with morbidity risks up to 91%, recurrence risks up to 56% and mortality risks of up to 7% (page 425, col. 1). Disease is observed most frequently within the first few months, yet calves at all ages are at risk (page 425, col.1). Van Donkersgoed et al., teach the occurrence of pneumonia depends on different infectious agents such as *Pasturella haemolytica* and *Haemophilus somnus* (page 425, col. 1). Van Donkersgoed et al., teach the effects of vaccination protocols on passive immunity to *Pasteurella haemolytica* and *Haemophilus somnus*. Prevention and control of pneumonia is best achieved by maximizing the calf's immunity to the common infectious agents of pneumonia (page 425, col.1). Previous studies show passively acquired antibodies of *P. haemolytica* reduce the risk of pneumonia, while acquired

antibodies reduce the risk of pasteurellosis, a bacterial induced respiratory illness (page 425, col.1).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate antigens from a respiratory disease such an pneumonia taught by Van Donkersgoed et al., to the method of decreasing respiratory illnesses in animals as taught by Stolle et al., in order to provide more efficient passive immunization results while decreasing the risk of mortality and/or morbidity. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., teach the desire to produce the avian-derived immunoglobulins for pharmaceutical applications in the treatment of disease; while Van Donkersgoed et al., teach the need to reduce sickness and death in animals. Furthermore, one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al., teach primary immunization with multiple specific antigens, such as the respiratory organisms, wherein all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Finally it would have been prima facie obvious to combine the teachings of Stolle and Van Donkersgoed et al., to advantageously decrease animal respiratory illness and reduce the ability of the organisms to multiply after immunization while saving animals and preventing the expenses associated with animal sickness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 62, 77 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., and Van Donkersgoed et al., in view of Emery et al., (US Patent 5,420,253 published May 30, 1995).

The claims are drawn to the method wherein the mixture is made by a method comprising: inoculating female birds, in or about to reach their egg laying age with said organism mixture; allowing a period of time sufficient to permit the production in the bird of antibody containing contents in the bird's eggs to said organism mixture; harvesting the eggs laid by the birds; separating the entire contents of said harvested eggs from the egg shells; adding preservatives to prevent microbial growth and extend shelf-life; mixing the separated contents of said harvested eggs and, preservatives; pasteurizing the mixture of the separated contents storing the pasteurized mixture of the separated contents of said harvested eggs and preservatives on a carrier material.

Stolle et al., and Van Donkersgoed et al., have been discussed above, however neither specifically recite adding preservatives to prevent microbial growth and extend shelf-life.

Emery et al., teach immunizing a bird to provide passive immunity protection against a bacterial pathogen, such as with *Pasteurella multicoda* and Haemophilus species (col. 4, lines 3-3 and col. 9, lines 45-48). Emery et al., teach the avian-derived immunoglobulins provides a higher level of specificity and a reduced amount of undesirable side effects as compared to immunoglobulins derived from mammalian serum (col. 1, lines 10-15). Emery et al., teach immunization will stimulate the female bird to produce eggs containing a high level of the immunoglobulin of interest, resulting in eggs being separated and purified (col. 4, lines 45-50). Emery et al., teach albumen, IgM, IgA and IgG locations and separation from the shell and yolk (col. 4, lines 56-68). Emery et al., teach combining the egg resulting product with physiologically acceptable carriers, other additives, including preserving agents such as bacteriostats, fungistats and the like and adjuvants as necessary (col. 8, lines 22-35). The composition may be administered orally, parenterally, or by respiratory aerosolization (col. 9, lines 14-17).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate using preservatives as taught by Emery et al., to the method of decreasing respiratory illness in animals by inhibiting the ability of the organisms causing respiratory illness as taught by Stolle et al., and Van Donkersgoed et al., in order to provide more efficient passive immunization results. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., and Van Donkersgoed et al., teach the desire to produce the avian-derived immunoglobulins for pharmaceutical applications in the treatment of respiratory illness wherein the modification adds preservatives, extends shelf life and is

administered by aerolization. Furthermore, one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al., and Emery et al., teach primary immunization with multiple specific antigens, such as the respiratory organisms, wherein all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Finally, it would have been prima facie obvious to combine the teachings of Stolle, Van Donkersgoed et al., and Emery et al., to advantageously decrease respiratory illness in animals and inhibit the ability of respiratory causing organisms.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

6. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., Emery et al., and Van Donkersgoed et al., as applied to claim 61-62 above, and further in view of Nash et al., (US Patent Application Publication 2002/0098181).

Stolle et al., and Van Donkersgoed et al., have been discussed above, as teaching a method of decreasing respiratory illnesses in animals comprising: inhibiting the ability of microbial organisms causing respiratory illness to adhere and multiply in the animals' respiratory tract wherein the inhibition is generated by spraying the contents of an egg mixture comprising adherence inhibiting material produced in eggs laid by female birds, the birds inoculated with an organism mixture comprising one or more microbial organisms causing respiratory illness, wherein the egg mixture is sprayed into the respiratory tract of the animal to produce a mist that coats the nasopharynx of the respiratory tract and prevents the microbial organisms causing

respiratory illness from adhering to the mucous membrane and bronchi and alveolar cells of the animals respiratory tract; however neither specifically recite adding molasses to the contents of the harvested eggs.

Nash et al., teach a microbial adherence inhibitor in the form of fowl egg antibodies made by inoculating female birds with the immunogen, after a period of time sufficient to permit production on the bird of antibody to the target immunogen, harvesting the eggs which contain antibodies to the immunogen, separated the eggs from the shells, drying the egg contents and adding to the feed or water for the host animals [para. 0028]. Nash et al., teach the inhibitor product can be used in almost any kind of feeding program, and works well is feed additives such as molasses [para. 0034]. The antibody microbial inhibitor material may be stored or shipped on carrier materials such as soy beans hulls, boluses and/or tablets [para. 0037].

Example 20 teaches pasteurized egg products. Example 21 teach supplying the egg product in a dried formatted, using a carrier to help distribute the material in a uniform method, which makes it easier for mixing with standard feeds. A number of carriers can be used wherein the production is pasteurized and coated onto the carrier [para. 0065].

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate adding molasses to the contents of the egg product as taught by Nash et al., to the method of decreasing animal respiratory illness by inhibiting the ability of the organisms to adhere to mucous membranes, bronchi and alveolar cell as taught by the prior art references in order to better distribute the egg

product material in a uniform method to the receiving animals. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., and Nash et al., teach the production of avian-derived immunoglobulins for pharmaceutical applications in the method of decreasing respiratory illness in animals. Furthermore, one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al., and Van Donkersgoed et al., teach primary immunization with organisms known to cause respiratory illness, and all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., and Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Weiner et al., (US Patent 5,556,744 published September 17, 1996).

Stolle et al., and Van Donkersgoed et al., have been discussed above, none specifically recite adding the preservative potassium sorbate.

Weiner et al., teach generating peptides useful in vaccine compositions and for generating antibodies for therapeutic compositions by passive immunization (col. 11, lines 1-3). Weiner et al., teach vaccine compositions containing adjuvants, preservative, chemical stabilizers including potassium sorbate (col. 14, lines 1-8). Weiner et al., teach pharmaceutical compositions useful in passive immunization can include the same ingredients, and preservatives as those ingredients known for active immunization (col. 12, lines 51-56).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate the preservative potassium sorbate as taught by Weiner et al., to the method of decreasing respiratory illness as taught by the prior art references in order to act as a preservative within the pharmaceutically acceptable carrier. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., and Van Donkersgoed et al., teach the production of inhibition material for pharmaceutical applications in the treatment of respiratory illness. Furthermore, one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al., teach primary immunization with organisms that cause respiratory illness, followed by immunization with the egg product to another animal where all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would

have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., and Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Okuno et al., (US Patent 6,337,070).

Stolle et al., and Van Donkersgoed et al., have been discussed above, however neither teach the viruses being swine influenza virus.

Okuno et al., teach inoculation with respiratory viruses comprising swine influenza (H1N1, H3N2). Okuno et al., teach that influenza viruses H1N1 and H3N2 subtypes of the virus (col1, lines 25-30). Okuno et al., teach the need for antibodies takes having cross-recognizing ability for influenza virus A virus subparticles and has a virus neutralization activity (col.2, lines 22-25). It is well known in the art that people get sick from avian-human influenza viruses generated in pigs because pigs have vectors for both avian and human receptors, thus there is a need prevent interspecies transmission. Okuno et al., teaches the need for a safe vaccine (col.2, lines 20-22).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate inoculation with respiratory swine influenza viruses comprising swine influenza (H1N1, H3N2) as taught by Okuno et al., to the method of Stolle et al., in order to have antibody containing contents that have recognizing ability for influenza virus. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., and Van Donkersgoed et al., teach the desire to produce egg mixtures useful for decreasing respiratory illness in animals. Furthermore, one having ordinary skill in the art would have been motivated to do this because Stolle et al., and Okuno et al., teach immunization with viral antigens. Finally it would have been prima facie obvious to combine the invention of Stolle et al., Van Donkersgoed and Okuno et al., to advantageously achieve a decrease in respiratory illness in animals against infectious swine influenza virus.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 recites the limitation "the organism mixture" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 80 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method wherein the birds are separated into different groups, each group of birds inoculated with a different microbial organism of the organism mixture and the egg mixture comprises adherence inhibiting material from all of the groups of birds.

Applicant did not point to support in the specification for a method where the birds are separated into different groups, each group of birds inoculated with a different microbial organism of the organism mixture and the egg mixture comprises adherence inhibiting material from all of the groups of birds. Moreover, applicant failed to specifically point to the identity of a method where the birds are separated into different groups, each group of birds inoculated with a different microbial organism of the organism mixture and the egg mixture comprises adherence inhibiting material from all of the groups of birds.

Thus, there appears to be no teaching of the instantly claimed method. Applicant has pointed to paragraphs [0026], [0028], [0033] and example 12 of the instant specification and original claims for support of the amendment, however it appears that the entire specification appears to fail to recite support for the newly recited method. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity of a method wherein the birds are separated into different groups, each group of birds inoculated with a different microbial organism of the organism mixture and the egg mixture comprises adherence inhibiting material from all of the groups of birds as recited by the newly added claim. Therefore, the new claim incorporates new matter and is accordingly rejected.

Conclusion

11. No claims allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor Patricia Duffy, can be reached on 571-272-0855. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645